Remarks

This amendment is in response to the Office Action mailed June 21, 2001.

The Examiner asked whether WO 98/18719 of Rudin et al. corresponds to this application. Please kindly note that it doe NOT correspond to this application, but corresponds to US Patent Application 09/297,189.

Rejection under 35 USC 102

Claims 1 to 8 and 10 stand rejected as being anticipated by the patents to Sangi, Atsumi et al (Atsumi), and Rudin et al (Rudin '133). Sangi and Atsumi are corresponding patents.

Valid rejection under 35 USC 102 requires that each feature of the rejected claims be disclosed in a single reference. None of the cited patents disclose each of features of the rejected claims 1 to 8 or 10.

The Examiner asserts that the compositions claimed in claims 1 to 7 differ from Rudin. only by the intended use of the composition. This assertion is based on the HAP particle size disclosed in Rudin '133. However, this assertion overlooks that the <u>particle shape</u> is essential for the composition and the particle size is of minor importance. In fact, none of the cited prior art teaches characteristically shaped HAP particles in the composition. Additionally, the production of HAP particles according to the state of the art involves milling or grinding larger crystals in order to obtain micron sized particles (see e.g., Rudin '133, page 1, last paragraph). Since all forms of apatite have indistinct cleavage, it is not possible to produce highly anisotropically shaped HAP particles just by milling or grinding. Therefore, the specifically sized and shaped particles as claimed in claim 1 are not anticipated by any one of the cited art.

In turn, the claimed composition does not merely distinguish from the prior art by intended use, as has been asserted by the Examiner, but rather, comprises a completely new and

Sangi (Atsumi)

inventive ingredient.

Sangi describes a dental composition including hydroxyapatite (HAP) having an overall particle size from 0.05 μ m to 1.0 μ m (see abstract).

In that composition, the hydroxyapatite serves to bond fluorine atoms and to provide recalcification of teeth (see column 2, line 51 to column 3, line 8).

However, the present invention claims a composition for stomatic applications with different shape (and size) of HAP particles. Present claim 1 defines a composition comprising HAP particles with an average

> length of 0.2 µm to 0.01 µm width of 0.01 µm to 0.1 µm thickness of 0.0001 µm to 0.1 µm.

This claimed specific shape and size of the HAP particles provide the advantageous properties of the present composition described in the specification.

Furthermore, an object of the present invention is to

"create a stomatic composition being identical to the basic substance of the dental enamel in its substance contents and crystalline parameters" (see page 2, paragraph 4, lines 1 to 4).

The present inventors found that the particle configuration, i.e. the specific ranges of length, width and thickness of the presently claimed particles, are adapted to the maximum to the dental enamel structure, being well suited as a building material e.g. for curing micro-defects (see page 3, paragraph 5, lines 5 to 7 of the specification).

Moreover, the shape of the composition of the present invention actively prevents inflammative-destructive diseases of the paradentium such as parodenitis and praradentosis in the tooth enamel (see page 3, paragraph 6, lines 6 to 8 of the specification). For example, this preventive activity to the dental enamel is caused by a high sorption activity relative to the paradontium tissue, which is, in turn, a result of the specific shape of the HAP particles.

As neither the presently claimed size nor shape are disclosed or rendered obvious by Sangi, present claim 1 is believed allowable over Sangi.

Furthermore, present claim 4 defines a composition for stomatic applications having a specific surface of HAP particles from 100 to 150 m²/g. No disclosure or hint concerning any value of the specific surface is disclosed in Sangi.

Therefore, claim 4 also is believed allowable over Sangi.

<u>Rudin '133</u>

Rudin '133 describes a preparation for stimulating growth in bone tissue.

In contradiction thereto, the present invention defines a composition for stomatic applications.

Moreover, Rudin '133 merely describes an overall particle size of $0.015~\mu m$ to $0.06~\mu m$. Rudin neither discloses renders obvious the presently claimed size or shape.

Therefore, the present claims are believed allowable over Rudin '133.

Summarizing, independent claims 1 to 4 and, therewith, dependent claims 2, 3 and 5 to 10 are believed allowable in view of the above-discussed prior art.

Rejection under 35 USC 103(a)

Claims 1-8 and 10 stand rejected as being unpatentable over Rudin taken with Atsumi (or Sangi) in view of dentifrices with claim 8 and claim 10 agents with layer particle size hydroxyapatite, cumulative to the admitted prior art set forth on page 1 (as noted above), in each of Scheller (I-II), Bristow et al (I-II-III), Coulson (I-II) and Aoki.

Valid rejection under 35 USC 103(a) requires that the prior art references provide motivation to a person skilled in the art to combine the references to produce the claimed invention.

The cited prior art does not provide such motivation, as explained in the above-discussion of the prior art.

There is no hint in the prior art cited by the Examiner to use anisotropically shaped HAP particles. Therefore, a compound as disclosed in the claims of the present invention is not rendered obvious, even by combining all of the cited art. Even an arbitrary combination of the cited art does not result in one of the claimed compositions. A combination would merely yield a composition comprising inhomogeneously <u>sized</u> HAP particles instead of comprising anisotropically <u>shaped</u> HAP particles.

In particular, the specific shape of the particles supports adhesion to the enamel. The compound as claimed in the application should, therefore, be deemed new and inventive.

An Abstract of the Disclosure is submitted on a separate sheet.

Claim 9 is not rejected on prior art. New independent claim 11 combines claim 9 and claim 1 on which claim 9 depends. We respectfully believe new claim 11 is therefore allowable.

We have amended claim 10 and independent claim 11 as the Examiner suggested to clarify that effective amounts of agents enhancing the gingivitis system of the mouth cavity are

included. This change was not made for reasons of patentability as meant by the Festo decision because inclusion of such agents would necessarily mean effective amounts rather than ineffective amounts.

Wherefore, further consideration and allowance of the claims in this application is respectfully requested.

Respectfully submitted,

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I hereby certify this correspondence is being deposited with the U.S Postal Service as a first class mail in an envelope with adequate postage addresses to Commissioner for Patents, Washington, D.C. 20231 on September 21, 2001.

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Marked-Up Version Showing Changes Made in this Amendment

[Claims:]

What is claimed is:

- 1. A stomatic composition characterised in that it comprises particles of hydroxyapatite with an average particle size in length (1), width (d) and thickness (h) of: 1 from about [0,2] $\underline{0.2}$ μm to about [0,01] $\underline{0.01}$ μm , d from about [0,1] $\underline{0.1}$ μm to 0.001, and h from about 0.1 μm to about [0,0001] $\underline{0.0001}$ 1 μm .
- The stomatic composition according to claim 1 characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of about $1 = [0.06] \ 0.06 \ \mu m +/- 50\%$, $d = [0.015] \ 0.015 \ \mu m +/- 50\%$ and $h = [0.005] \ 0.005 \ \mu m +/- 50\%$.
- 3. The stomatic composition according to claim 1 characterised in that it comprises particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of about $1 = [0.06] \ \underline{0.06} \ \mu m$, $d = [0.015] \ \underline{0.015} \ \mu m$, $h = [0.005] \ \underline{0.005} \ \mu m$.
- 4. A stomatic composition characterised in that it comprises particles of hydroxyapatite having a specific surface of [hydroxiapatite] hydroxyapatite from about 100 m²/g to about 150 m²/g.
- 5. The stomatic composition according to claim 1 characterized in that it comprises said hydroxyapatite particles ultra finely divided.
- 6. The composition according to claim 1 characterised in that the ultra finely divided hydroxyapatite particles are present in the composition in an amount of [0,1] <u>0.1</u>% to 50% by weight.

- 7. The composition according to claim 1 characterised in that the ultra finely, divided hydroxyapatite is a synthetic hydroxyapatite which contains [99,9] 99.9% of Ca₁₀(PQ₄)₆(OH)₂ by weight.
- 8. The composition according to claim 1 further characterised by at least one substance of the group consisting of
 - humectants in a range from about 0% to 85% by weight,
 - bindings and thickeners in a range of 0% to 10% by weight,
 - abrasive materials in a range from 0.0% to 25%,
 - Surfactants in a range from 0% to 5% by weight,
 - Flavours in a range from 0% to 5% by weight.
- 9. The composition according to claim 1 further characterised by agents enhancing the gingivitis system of the mouth cavity and comprising extracts of natural plants including at least one of the group consisting of urtica, millefolium, chamomilla hypericum, salvia, etc. in the aqueous and in the aqueous-alcoholic form.
- 10. The composition according to claim 1 further characterised by <u>effective amounts of antimicrobial and anti-plaque agents.</u>
- 11. A stomatic composition comprising particles of hydroxyapatite with an average particle size in length (I), width (d) and thickness (h) of: I from about 0.2 μm to about 0.01 μm, d from about 0.1 μm to about 0.001 μm, and h from about 0.1 μm to about 0.0001 μm, and effective amounts of gingivitis systems of the mouth cavity comprising extracts of natural plants including at least one of the group consisting of urtica, millefolium, chamomilla hypericum, and salvia, in an aqueous or an aqueous-alcoholic form.

Abstract of the Disclosure

A stomatic composition has particles of hydroxyapatite with an average particle size in length (l), width (d) and thickness (h) of : l from about 0.2 μm to about 0.01 μm, d from about 0.1 μm to about 0.001 μm, and h from about 0.1 μm to about 0.0001 μm.